

CLAIMS

What is claimed is:

1. A combination medical device comprising:
 - a) a circular stapler instrument, comprising a staple cartridge component
5 and corresponding anvil component, and
 - b) one or more portions of buttress material adapted to be a) stably positioned upon the staple cartridge and/or anvil components of the stapler prior to, or at the time of, use, b) while in position upon the stapler component(s), to then be delivered to a tissue site in combination with the stapler components, c) upon delivery
10 of the components and positioned material portion(s) to the tissue site, to provide a first region of buttress material as a staple line buttress seal between joined tissue sections upon activation of the stapler, and optionally, d) to permit the removal of one or more portions of the second region of the buttress material upon activation of a stapler knife provided by the stapler.
- 15 2. The combination according to claim 1 wherein the buttress material comprises preformed animal tissue.
3. The combination according to claim 2 wherein the preformed animal
20 tissue comprises pericardium.
4. The combination according to claim 3 wherein the pericardium has been formed by a process that includes the steps of forming the pericardium onto a mandrel or other model shape, soaking the formed pericardium in a crosslinking
25 solution, removing the pericardium from the mandrel or other model shape, and sterilizing the pericardium.
5. The combination according to claim 1 wherein the buttress material is provided as a plurality of portions, including one portion adapted to fit the staple
30 cartridge and another portion adapted to fit the anvil component.

6. The combination according to claim 5 wherein the buttress material portions each comprise two or more regions, including a first region adapted to serve as the staple line buttress itself, together with a second region adapted to assist in positioning and/or retaining the buttress material upon a stapler component.

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7. The combination according to claim 6 wherein one or more portions of the second region are adapted to be removed from the tissue site upon formation of the staple seam and activation of a stapler knife.

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8. The combination according to claim 7 wherein the second region is generally concentric to the first region, the first and second regions cooperating to provide a desired three dimensional and/or topographic structure adapted to position and/or retain the materials in place upon the respective stapler component.

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9. The combination according to claim 8 wherein the first region and the second region of at least one buttress material portion comprises dissimilar materials.

10. The combination according to claim 9 wherein the first region comprises animal tissue and the second region comprises a polymer.

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11. The combination according to claim 9 wherein the first region comprises non-crosslinked, mammalian tissue.

12. A kit for use in a circular stapling procedure employing a circular stapler that comprises a staple cartridge component and a corresponding anvil component,

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the kit comprising one or more portions of buttress material adapted to be a) stably positioned upon the staple cartridge and/or anvil components of the stapler prior to, or at the time of, use, b) while in position upon the stapler component(s), to then be delivered to a tissue site in combination with the stapler components, c) upon delivery of the components and positioned material portion(s) to the tissue site, to provide a first region of buttress material as a staple line buttress seal between joined

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tissue sections upon activation of the stapler, and optionally, d) to permit the removal of one or more portions of the second region of the buttress material upon activation of a stapler knife provided by the stapler.

5 13. The kit according to claim 12 wherein the buttress material comprises preformed animal tissue.

 14. The kit according to claim 13 wherein the preformed animal tissue comprises pericardium.

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 15. The kit according to claim 14 wherein the pericardium has been formed by a process that includes the steps of forming the pericardium onto a mandrel or other model shape, soaking the formed pericardium in a crosslinking solution, removing the pericardium from the mandrel or other model shape, and sterilizing the
15 pericardium.

 16. The kit according to claim 12 wherein the buttress material is provided as a plurality of buttress material portions, including one portion adapted to fit the staple cartridge and another portion adapted to fit the anvil component.

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 17. The kit according to claim 16 wherein the buttress material portions each comprise two or more regions, including a first region adapted to serve as the staple line buttress itself, together with a second region adapted to assist in positioning and/or retaining the buttress material portion upon a stapler component.

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 18. The kit according to claim 17 wherein one or more portions of the second region are adapted to be removed from the tissue site upon formation of the staple seam and activation of a stapler knife.

30 19. The kit according to claim 18 wherein the second region is generally concentric to the first region, the first and second regions cooperating to provide a

desired three dimensional and/or topographic structure adapted to position and/or retain the materials in place upon the respective stapler component.

20. The kit according to claim 19 wherein the first region and the second
5 region comprise dissimilar materials.

21. The kit according to claim 20 wherein the first region comprises animal tissue and the second region comprises a polymer.

10 22. The kit according to claim 20 wherein the first region comprises non-crosslinked, mammalian tissue.

23. A method of performing a surgical stapling procedure, the method comprising the steps of providing a combination according to claim 1, and employing
15 the stapler and buttress material to provide a buttressed surgical seam between abutting tissue portions.

24. The method according to claim 23 wherein the buttress material comprises preformed animal tissue.

20 25. The method according to claim 24 wherein the preformed animal tissue comprises pericardium.

26. The method according to claim 25 wherein the pericardium has been
25 formed by a process that includes the steps of forming the pericardium onto a mandrel or other model shape, soaking the formed pericardium in a crosslinking solution, removing the pericardium from the mandrel or other model shape, and sterilizing the pericardium.

30 27. The method according to claim 23 wherein the buttress material portions are provided as a plurality of portions, including one portion adapted to fit the staple cartridge and another portion adapted to fit the anvil component.

28. The method according to claim 27 wherein the buttress material portions each comprise two or more regions, including a first region adapted to serve as the staple line buttress itself, together with a second region adapted to assist in positioning and/or retaining the buttress material upon a stapler component.

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29. The method according to claim 28 wherein one or more portions of the second region are adapted to be removed from the tissue site upon formation of the staple seam and activation of a stapler knife.

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30. The method according to claim 29 wherein the second region is generally concentric to the first region, the first and second regions cooperating to provide a desired three dimensional and/or topographic structure adapted to position and/or retain the materials in place upon the respective stapler component.

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31. The method according to claim 30 wherein the first region and the second region of at least one buttress material comprises dissimilar materials.

32. The method according to claim 31 wherein the first region comprises animal tissue and the second region comprises a polymer.

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33. The method according to claim 31 wherein the first region comprises non-crosslinked, mammalian tissue.

34. The method according to claim 23 wherein the buttressed surgical seam between abutting tissue portions is created without first binding said abutting tissue portions with one or more sutures.

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35. The method according to claim 28 wherein one or more retaining rings are used to help retain the abutting tissue portions on the buttress materials.

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36. The method according to claim 35 further including the step of using a tissue push tool to place the one or more retaining rings.

37. A method of forming a buttress material for use in a kit according to claim 12, the method comprising the steps of treating the buttress material positioned upon a form of suitable size and shape to approximate that of a surgical stapler component.

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38. The method according to claim 37 wherein the buttress material comprises preformed animal tissue.

39. The method according to claim 38 wherein the preformed animal tissue comprises pericardium.

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40. The method according to claim 39 wherein the pericardium has been formed by a process that includes the steps of forming the pericardium onto a mandrel or other model shape, soaking the formed pericardium in a crosslinking solution, removing the pericardium from the mandrel or other model shape, and sterilizing the pericardium.

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41. A method of forming a buttress material portion for use in a kit according to claim 12, the method comprising the steps of preparing a plurality of portions, including one portion adapted to fit the staple cartridge and another portion adapted to fit the anvil component.

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42. The method according to claim 41 wherein the buttress material portions each comprise two or more regions, including a first region adapted to serve as the staple line buttress itself, together with a second region adapted to assist in positioning and/or retaining the buttress material upon a stapler component.

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43. The method according to claim 42 wherein one or more portions of the second region are adapted to be removed from the tissue site upon formation of the staple seam and activation of a stapler knife.

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44. The method according to claim 43 wherein the second region is generally concentric to the first region, the first and second regions cooperating to provide a desired three dimensional and/or topographic structure adapted to position and/or retain the materials in place upon the respective stapler component.

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45. The method according to claim 44 wherein the first region and the second region comprise dissimilar materials.

46. The method according to claim 45 wherein the first region comprises animal tissue and the second region comprises a polymer.

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47. The method according to claim 45 wherein the first region comprises non-crosslinked, mammalian tissue.

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48. The method according to claim 47 further including the step of attaching the first region to the second region by welding, friction, adherence, tacking, or tongue-in-groove attachment.

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49. A circular stapler buttress material comprising buttress material adapted to be

a) stably positioned upon at least one stapler component of a circular stapler prior to, or at the time of, use,

b) while in position upon the stapler component(s), to then be delivered to a tissue site in combination with the stapler component(s),

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c) upon delivery of the stapler components and positioned buttress material to the tissue site, to provide a first region of buttress material as a staple line buttress seal between joined tissue sections upon activation of the stapler, and optionally,

d) to permit the removal of a second region of the buttress material upon activation of a stapler knife provided by the stapler.

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50. The circular stapler buttress material of claim 49, wherein the circular stapler buttress material is adapted to be stably positioned on a staple cartridge component.

5 51. The circular stapler buttress material of claim 49, wherein the circular stapler buttress material is adapted to be stably positioned on a staple anvil component.

10 52. The circular stapler buttress material of claim 50, wherein the buttress material is a homogenous buttress material comprising a single type of material.

53. The circular stapler buttress material of claim 50, wherein the buttress material is a composite buttress material comprising two or more types of material.

15 54. The circular stapler buttress material of claim 51, wherein the buttress material is a homogenous buttress material comprising a single type of material.

20 55. The circular stapler buttress material of claim 51, wherein the buttress material is a composite buttress material comprising two or more types of material.

56. The circular stapler buttress material of claim 53 wherein the buttress material comprises two or more regions, including a first region adapted to serve as a staple line buttress, together with a second region adapted to assist in positioning and/or retaining the first region upon the stapler cartridge component.

25 57. The circular stapler buttress material of claim 56 wherein the first region comprises tissue in the form of sterilized pericardium, and the second region is generally concentric to the first region, the first and second regions cooperating to provide a desired three dimensional and/or topographic structure adapted to position and/or retain the buttress material upon the stapler cartridge component.

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58. The circular stapler buttress material of claim 57 wherein the first and second regions are adapted to be separated upon activation of a stapler knife, in a manner sufficient to permit the separated first region to provide a buttressed surgical seam between abutting tissue portions and to permit the separated second region to be removed from the tissue site.